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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,884	02/14/2001	Christopher J. Berry	57897-5005	3367

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

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DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/783,884

Applicant(s)

BERRY ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 34-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 5. 6) ☐ Other: _____

DETAILED ACTION

This application is a divisional of Serial No. 09/411,591 which claims priority to provisional application Serial No. 60/104,227.

Election/Restrictions

Applicant's election with traverse of the invention of Group II, claims 34-48, in Paper No. 9 submitted January 22, 2002 is acknowledged.

The traversal is on the ground(s) that the Restriction Requirement is not appropriate. Applicant asserts that "the Examiner states that other products, e.g. statins, can be used a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human. However, claim 34 specifically requires the use of the edible oil to reduce serum cholesterol..". Applicant's assertion is not found persuasive. As discussed in the "Restriction Requirement" in the previous Office Action mailed November 11, 2001(see page 2), in the instant case, for example, a statin may be used a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human. Therefore, the criteria for distinct inventions: (1) the process for using the product as claimed can be practiced with **another materially different product** is met since a statin is another materially different product -- which is materially different from the product as claimed, the edible oil herein, as Applicant asserts in this remarks.

Therefore, the inventions of Groups I and II are seen to be separate and distinct inventions properly restricted from each other. Further, the search for the inventions of

Art Unit: 1617

both Groups I and II would place an undue burden on the Office. Note regarding the classification of the inventions herein that the search is not limited to the patent files. The search field for a composition is non-coextensive with the search field for a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103. The composition and method herein have separate consideration as to patentability.

Further, the traversal is on the ground(s) that the Restriction Requirement herein is different from the Restriction Requirement in the parent application (Serial No. 09/411,591, US 6,277,431) by the other Examiner, in which there was no restriction between Group I and II herein. This is also not found persuasive. For the reasons set forth above, the inventions of Groups I and II are seen to be separate and distinct inventions. Note that an examiner is not prohibited from making a new restriction during the prosecution of a patent application and the examiner herein is not bound by the parent application prosecution herein.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Objection

Claims 38-43 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is well settled that recitation of an inherent property of a composition or method will not further limit claims drawn to a composition or method. In the instant case, for example, "decreases total serum cholesterol and serum LDL cholesterol by 5-25% and increases serum HDL cholesterol by 10-30%" in claims 38-40, is an inherent property of the composition herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34-43 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the composition in claim 1. Note that both claims 1-23 are withdrawn from further consideration. Insertion of the recitation of compositions of claims 1 into claim 34 would be favorably considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34, 36, and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Jandacek (3,865,939, PTO-892).

Jandacek discloses that the edible oil therein is useful in a composition and a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human and that this edible oil in the composition with effective amounts of active ingredients is administered in the form of a food product such as cooking, salad oil or foodstuffs. See abstract, col.1 lines 5-26, and claims 1-7. Jandacek also discloses that this edible oil composition comprises plant sterols (sterols and stanols) in 2.0-6.0% wt, which is known to inhibit or suppress cholesterol in the blood. See abstract, col.1-2, and Table 1 at col.3-4. Thus, Jandacek anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35, 37-43 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek (3,865,939, PTO-892) and Imai et al. (5,514,398, PTO-892) and Lane et al. (PTO-1449 submitted April 27,2001)

Jandacek discloses that the edible oil therein is useful in a composition and a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human and that this edible oil in the composition with effective amounts of active ingredients is administered in the form of a food product such as cooking, salad oil or foodstuffs. See abstract, col.1 lines 5-26, and claims 1-7. Jandacek also discloses that this edible oil composition comprises plant sterols (sterols and stanols) in 2.0-6.0% wt, which is known to inhibit or suppress cholesterol in the blood. See abstract, col.1-2, and Table 1 at col.3-4.

Imai et al. discloses that sterols such as campesterol stigmasterol, sitosterol, and cycloarterol and triterpene alcohol is useful as food additives in a food composition (food product) and a method of reducing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human. See abstract, col.1 line 33 to col.2 line 22, col. 22-26, and claim 3.

Lane et al. discloses that tocotrienols and tocotrienol-like compounds are useful as food additives in a food composition (foodstuff) and a method of decreasing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human and tocotrienols and tocotrienol-like compounds also have antioxidant activity. See abstract and claims 8-11 and 21-25.

The prior art does not expressly disclose further adding cycloarterol and tocortrienols (triterpene alcohol) into the edible oil of Jandacek. The prior art does not also expressly disclose that the edible oil decreases the blood triglyceride level, total serum cholesterol, and serum LDL cholesterol by 5-25% and increases serum HDL cholesterol by 10-30%, and decreases serum level of peroxides by 10-60%, and raises serum level of tocotrienol by 20-110%.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to further add cycloarterol and tocortrienols (triterpene alcohol) into the edible oil of Jandacek, and to expect the edible oil to decrease the blood triglyceride level, total serum cholesterol, and serum LDL cholesterol by 5-25% and to increase serum HDL cholesterol by 10-30%, and to decrease serum level of peroxides by 10-60%, and to raise serum level of tocotrienol by 20-110%.

One having ordinary skill in the art at the time the invention was made would have been motivated to further add cycloarterol and tocortrienols (triterpene alcohol) into the edible oil of Jandacek since cycloarterol and tocortrienols are known to be useful as food additives in a food composition (foodstuff) and a method of decreasing total serum cholesterol and serum LDL cholesterol and raising serum HDL cholesterol in a human based on the prior art. Therefore, one of ordinary skill in the art would have reasonably expected that further add cycloarterol and tocortrienols (triterpene alcohol) into the edible oil of Jandacek known to be useful individually for the same purpose, i.e., decreasing total serum cholesterol and serum LDL cholesterol and raising serum HDL

cholesterol in a human, in a composition to be administered would improve the therapeutic effect for treating hypercholesterol in human.

Since all active composition components herein are known to be useful to treat and prevent hypercholesterol in human, it is considered *prima facie* obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Additionally, one of ordinary skill in the art would have reasonably expected that the edible oil herein would lower the blood triglyceride level, total serum cholesterol, and serum LDL cholesterol by 5-25% and increase serum HDL cholesterol by 10-30%, and decrease serum level of peroxides by 10-60%, and raise serum level of tocotrienol by 20-110% since the active components in the edible oil composition herein would exhibit their known therapeutic effects in the human.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
February 21, 2002


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